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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,526	11/21/2001	Yasushi Shigemori	032735-004	9938

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EXAMINER	
STRZELECKA, TERESA E	
ART UNIT	PAPER NUMBER
1637	8

DATE MAILED: 12/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/989,526	SHIGEMORI ET AL.	
	Examiner	Art Unit	
	Teresa E Strzelecka	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10 is/are rejected.

7)☒ Claim(s) 1-9 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of the Japanese Patent No. 2000/386361 has been received on July 12, 2002 and was placed in the application.

Specification

2. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are:

A) The first sentence of the specification: "Differences of various phenotypes of human including disease are known to be derived from the differences of DNA nucleotide sequence in individual genome, which is called single nucleotide polymorphism.".

B) Page 2, lines 11-13.

C) Page 3, line 31: "When polymorphism is existed in the test DNA region...".

D) Page 4, lines 15-16.

E) Page 5, line 14: "... the followings:...".

F) Page 6, line 26: "... oligonucleotide consisting sequence complementary to the DNA...". The same problem is present on page 7, line 19, 36; page 8, line 26; page 9, line 19; page 11, line 22 and 30; page 15, line 33; page 17, line 23; page 19, line 1.

G) Starting from the description of gel lanes in Figure 4 (page 8), and continuing through Fig. 6, 9, 10, 12 and 13, lane descriptions state that a particular oligonucleotide or heat

treatment was not used, whereas it is clear from the description of the experiments further in the specification that they were used. Applicants use the term "... without using...".

H) Page 20, lines 8-10: "The polymorphism consisting the difference of a nucleotide is preferred in this invention.".

I) Page 32, line 14-15: "... 80~20 mer oligonucleotide".

3. The Brief Description of Drawings does not contain separate descriptions of Fig 2A and 2B, 3A and 3B, 4A and 4B, 6A and 6B, 9A and 9B, 10A and 10B, 12A and 12B.

Claim Objections

4. Claims 1-9 are objected to because of the following informalities: claims end in commas rather than in periods. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-8 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 1 is indefinite over the recitation of the limitation "...(d) detecting an oligonucleotide probe that binds to the double strand DNA to form the triple strand DNA,". In step (c) the probe is released from the triple strand when it is not complementary to the polymorphic site, therefore it is not clear what probe is being detected.

B) Claim 10 is indefinite over the recitation of the limitation "... further comprising at least one selected from the group consisting of..." (emphasis added).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 9 and 10 are rejected under 35 U.S.C. 102(a) as being anticipated by Pati et al. (U.S. Patent No. 6,200,812 B1).

Pati et al. teach a kit including DNA probes, recombinases, buffers and ATP (col. 35, lines 67-67; col. 36, lines 1-3).

9. Claims 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Pati et al. (U.S. Patent No. 6,074,853).

Pati et al. teach a kit including DNA probes, recombinases, buffers and ATP (col. 38, lines 1-5).

10. Claims 9 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Pati et al. (U.S. Patent No. 6,200,812 B1).

Pati et al. teach a kit including DNA probes, recombinases, buffers and ATP (col. 35, lines 67-67; col. 36, lines 1-3).

11. Claims 9 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Kigawa et al. (U.S. Patent No. 6,335,164 B1).

Kigawa et al. teach a kit comprising a RecA-like recombinase, appropriate co-factors, a heterologous and homologous probes and washing solution (col. 11, lines 53-59; claims 42, 43, 46-58).

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

13. Claims 9 and 10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 9 of copending Application No. 09/549,949. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 9 of the 09/549,949 application is a species of claims 9 and 10 of the current application. In other words, claim 9 of the 09/549,949 application falls within the scope of claims 9 and 10 of the current application, therefore claims 9 and 10 of the current application are

anticipated by claim 9 of the 09/549,949 application. Specifically, claim 9 of the 09/549,949 application is drawn to a kit comprising a nuclease, a homologous recombination protein, nucleoside triphosphate or its analogue and optionally a buffer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. No references have been found teaching or suggesting claims 1-8, but they are rejected for other reasons.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

December 20, 2002

Teresa Strzelecka

Patent Examiner

Teresa Strelecka
12/20/02